

Attorney Docket No.: 37697-0080

Applicant(s) Edward W. MERRILL et al.

Confirmation No.: To be assigned

Appl. No.:

10/696,709

Group Art Unit: To be assigned

Filing Date:

October 30, 2003

Examiner: To be assigned

Title:

RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR

WEIGHT POLYETHYLENE PROSTHETIC DEVICES

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56 and 37 CFR §1.97

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents are being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

Applicants believe that the instant Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits under 37 CFR §1.97(b)(3), therefore, no fee is required in connection with its filing.

U.S. Serial No. 10/696,709

Applicants submit herewith on Form Form PTO/SB/08A, a listing of the documents cited by or submitted to the Patent Office in parent application Serial No. 09/764,445 filed January 19, 2001. The relevance of these prior art documents is explained in the parent application.

As provided in 37 C.F.R. §1.98(d), copies of the documents are not being provided since they were previously cited by or submitted to the Patent Office in parent application Serial No. 09/764,445 filed January 19, 2001.

English translations of the foreign-language documents may not be readily available; however, the absence of such translations does not relieve the PTO from its duty to consider the submitted documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,

June 15, 2004 Date

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Fax: (202) 912-2020 Customer No. 26633 Sheet 1 of 5 SERIAL NO. ATTY DOCKET NO. FORM PTO/SB/08A 10/696,709 PADEMARY 37697-0080 APPLICANT LIST OF REFERENCES CITED Edward W. MERRILL et al. BY APPLICANT(S) **FILING DATE** GROUP To be assigned Date Submitted: June 15, 2004 October 30, 2003 **U.S. PATENT DOCUMENTS** CLASS SUBCLASS FILING DATE IF *EXAMINER DOCUMENT DATE NAME **APPROPRIATE** (M/D/Y)INITIAL NUMBER 23 1/9/90 AINSWORTH ET AL. 623 A01 4,892,552 8/27/96 AVERILL ET AL. 623 22 A02 5,549,698 BASHIR ET AL. 526 352 3/19/91 5,001,206 A03 BASTIAANSEN ET AL. 522 161 A04 5,428,079 6/27/95 CHABROL ET AL. 427 2.26 5,480,683 1/2/96 A05 606 99 10/22/91 COATES 5,059,196 A06 DEARNALEY 427 2.26 5,593,719 1/14/97 A07 603 22 80A 4,524,467 6/25/85 **DECARLO** 428 411.1 11/14/95 ENGLAND ET AL. A09 5,466,530 22 GAUSSENS ET AL. 623 A10 4,747,990 5/31/88 22 8/27/96 GRAHAM ET AL. 623 5,549,700 A11 522 189 2/6/01 HAMILTON ET AL. 6,184,265 A12 23 5/19/98 HIGGINS 422 A13 5,753,182 5,478,906 12/26/95 HOWARD 526 352 A14 HOWARD ET AL. 528 481 11/4/97 A15 5.684,124 18.11 1/2/01 HYON ET AL. 623 A16 6,168,626 6,506,866 1/14/03 JACOBSEN ET AL. 526 348 A17 JOHNSTON ET AL. 21 54 3,758,273 9/11/73 A18 KOLTHAMMER ET AL. 525 240 A19 5,869,575 2/9/99 A20 5,066,755 11/19/91 LEMSTRA 526 348.1 352 526 A21 5,037,928 8/6/91 LI ET AL. 352 3,944,536 LUPTON ET AL. 526 A22 3/16/76

DATE CONSIDERED

EXAMINER

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Sheet 2 of 5 ATTY DOCKET NO. SERIAL NO. Form PTO/SB/08A 37697-0080 10/696,709 APPLICANT LIST OF REFERENCES CITED Edward W. MERRILL et al. BY APPLICANT(S) **GROUP** FILING DATE To be assigned Date Submitted: June 15, 2004 October 30, 2003 U.S. PATENT DOCUMENTS SUBCLASS CLASS **FILING DATE IF** *EXAMINER DOCUMENT DATE NAME **APPROPRIATE NUMBER** INITIAL (M/D/Y)MCKELLOP ET AL. 623 18 A23 6,165,220 12/26/00 A24 6,245,276 6/12/01 MCNULTY 264 322 A25 5,358,792 10/25/94 MEHTA ET AL. 428 516 3/9/99 MERRILL ET AL. 623 22 A26 5,879,400 10/15/02 MERRILL ET AL. 264 485 A27 6,464,926 11/4/04 623 23.58 A28 6,641,617 MERRILL ET AL. 11/14/67 MEYER ET AL. 260 45.7 A29 3,352,818 12/21/99 PARIKH ET AL. 525 221 6,005,053 A30 10/26/99 PATEL ET AL. 428 35.2 A31 5,972,444 5/14/96 **PIENKOWSKI** 427 2.26 A32 5,515,590 5/6/86 RANDALL ET AL. 522 4,586,995 5 A33 8/20/85 ROBERTS ET AL. 623 22 A34 4,535,486 8/28/01 SALOVEY ET AL. 523 115 A35 6,281,264 1/25/00 161 A36 6,017,975 SAUM ET AL. 522 6,242,507 6/5/01 SAUM ET AL. 522 161 A37 6,316,158 11/13/01 SAUM ET AL. 430 130 A38 3,698,017 10/17/72 SCALES ET AL. A39 3 1 A40 5,824,411 10/20/98 SHALABY ET AL. 428 364 5/8/01 SHEN ET AL. 522 153 A41 6,228,900 6/23/92 SIOSHANSI ET AL. 623 16 A42 5,123,924 6/23/92 SMESTAD ET AL. 623 16 A43 5,123,925 **EXAMINER** DATE CONSIDERED

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Sheet 3 of 5 FORM PTO/SB/08A ATTY DOCKET NO. SERIAL NO. 10/696,709 37697-0080 APPLICANT LIST OF REFERENCES CITED Edward W. MERRILL et al. BY APPLICANT(S) GROUP **FILING DATE** October 30, 2003 To be assigned Date Submitted: June 15, 2004 U.S. PATENT DOCUMENTS SUBCLASS FILING DATE IF DOCUMENT DATE NAME **CLASS** *EXAMINER **APPROPRIATE** INITIAL NUMBER (M/D/Y)623 5.024,670 6/18/91 SMITH ET AL. 18 A44 SUN ET AL. 525 333.7 A45 5,414,049 5/9/95 A46 5,449,745 9/12/95 SUN ET AL. 528 483 7/22/97 SUN ET AL. 528 483 A47 5,650,485 3/17/98 SUN ET AL. 522 65 A48 5,728,748 1/16/01 SUN ET AL. 523 113 A49 6,174,934 333.7 8/6/96 SUN ET AL. 525 A50 5,543,471 5/31/83 TEINTURIER 3 1.912 A51 4,385,405 3/19/91 TOKITA ET AL. 428 400 A52 5,001,008 6,096,084 TOWNI FY 8/1/00 623 23.12 A53 11/3/92 WARD ET AL. 264 22 A54 5,160,464 3,297,641 1/10/67 WERBER ET AL. 260 66 A55 2/20/90 YAGI ET AL. 264 83 A56 4,902,460 4/7/87 ZACHARIADES ET AL. 623 1 A57 4,655,769 7/31/90 ZACHARIADES 428 36.1 4,944,974 A58 11/3/92 ZACHARIADES 264 136 A59 5,160,472 ZACHARIADES ET AL. 264 A60 5,407,623 4/18/95 119 FOREIGN PATENT DOCUMENTS DOCUMENT COUNTRY CLASS SUBCLASS **TRANSLATION** DATE NUMBER (M/D/Y) YES NO A61 WO01/05337 1/25/01 WIPO WO98/01085 1/15/98 WIPO A62 A63 WO97/29793 8/21/97 WIPO **EXAMINER** DATE CONSIDERED

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Sheet 4 of 5 SERIAL NO. FORM PTO/SB/08A ATTY DOCKET NO. 10/696,709 37697-0080 **APPLICANT** LIST OF REFERENCES CITED Edward W. MERRILL et al. BY APPLICANT(S) GROUP FILING DATE October 30, 2003 To be assigned Date Submitted: June 15, 2004 FOREIGN PATENT DOCUMENTS COUNTRY CLASS **SUBCLASS TRANSLATION** DOCUMENT DATE NO NUMBER (M/D/Y)YES Abstract A64 JP58157830 9/20/83 JAPAN EP0729981B1 9/4/96 **EUROPE** A65 EP0722973A1 7/24/96 **EUROPE** A66 EP0737481B1 10/16/96 **EUROPE** A67 A68 EP0373800B1 6/20/90 **EUROPE** Abstract A69 JP4198242 6/17/92 **JAPAN** JAPAN Abstract A70 JP4185651 7/2/92 OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.) SILANE CROSS-LINKED HDPE FOR PROSTHETIC APPLICATIONS, POLYMERS IN MED. AND ATKINSON A71 SURGERY, CONF. HELD BY PLASTICS & RUBBER INST. & BIOLOGICAL ENG. SOC. (1989) DIJKSTRA ET AL. POLYMER 30: 866-873 (1989) A72 RADIAT. PHYS. CHEM. 9: 647-652 (1977) A73 DU PLESSIS ET A74 GENT ET AL. J. OF POLMER SCI 5: 47-61 (1967) COLLOID & POLYMER SCI. 260: 742-753 (1982) A75 GIELENZ ET AL. GROBBELAAR J. OF BONE AND JOINT SURGERY 60-B(3): 370-374 (1978) A76 ET AL. GROBBELAAR SA BONE AND JOINT SURGERY IX(3): 143-147 (1999) A77 ET AL. A78 JAHAN ET AL. J. OF BIOMED RESEARCH 25: 1005-1016 (1991) J. OF LUMINESCENCE 40 & 41:242-243 (1988) A79 JAHAN ET AL. JONES ET AL. WEAR 70: 77-92 (1981) A80 KANG ET AL. J. OF AMER. CHEM. SQC. 89(9): 1980-1986 (1967) A81 MANDELKERN NATIONAL BUREAU OF STANDARDS 82: 46-53 (1960) A82 ET AL. **NUSBAUM ET** J. OF BOIMED MATERIAL RESEARCH 13: 557-576 (1979) A83 AL OONISHI ET AL. RADIA. PHYS. CHEM 39(6): 495-504 (1992) A84 ENCYCLOPEDIC HANDBOOK OF BIOMATERIALS AND BIOENGINEERING 2: 1853-A85 OONISHI ET AL. 1868 (1995) SUPER LOW WEAR CROSS-LINKED UHMWPE BY HEAVY HIGH-DOSE RADIATION, OONISHI ET AL. A86 WPOA 2ND CONGRESS OF HIP SECTION, PG. 61 (1996) ROSE ET AL. J. OF ORTHOPAEDIC RESEARCH SOCIETY 2(4): 393-400 (1984) A87 A88 SAUNDERS ET MEDICAL DEVICE & DIAGNOSTIC INDUSTRY 222:89-92 (1993) AL. **EXAMINER** DATE CONSIDERED

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Date Submitted: June 15, 2004				FILING DATE GROUP October 30, 2003 GROUP To be assigned				
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)								
-	A89	SHEN	Effect of Irradiation on Chemically Crosslinked Ultrahigh Molecular Weight Polyethylene (A Dissertation Presented to the Univ. of Southern California (December 1994))					
	A90	STREICHER	INVESTIGATION ON STERILIZATION AND MODIFICATION OF HIGH MOLECULAR WEIGHT POLYETHYLENES BY IONIZING IRRADIATION, BETA-GAMMA (1/89)					
	A91	ZOEPFL ET AL.	J. POLYMER SCI POLYM. CHEM. ED 22: 2017-2032 (1984)					
	A92	ZOEPFL ET AL.	J. POLYMER SCI POLYM. CHEM. ED 22: 2033-2045 (1984)					
	A93		AM SOC FOR TESTING AND MATERIALS, DESIGNATION: E1649-94, PGS. 870-888 (1995)					
	A94		COMPLAINT					
	A95		AMENDED COMPLAINT					
	A96		ANSWER OF DEFENDANTS MASSACHUSETTS INSTITUTE OF TECH. AND THE GENERAL HOSPITAL CORPORATION TO AMENDED COMPLAINT AND AMENDED COUNTER CLAIM					
	A97		REPLY OF PLAINTIFF, AMBUJ D. SAGAR, PH.D., TO AMENDED COUNTERCLAIM OF DEF. MASSACHUSETTS INSTITUTE OF TECHNOLOGY AND THE GENERAL HOSPITAL CORP.					
	A98		LONG TERM PERFORMANCE OF GAMMA IRRADIATED HDPE CUPS IN TOTAL HIP REPLACEMENT (1997) (ABSTRACT)					
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